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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,868	07/10/2003	Dominique Rigal	8076.294USW1	1456
23552	7590	03/27/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1655	
DATE MAILED: 03/27/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,868

Applicant(s)

RIGAL ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 18-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 and 18-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the preliminary amendment on January 26, 2004 with Applicant's cancellation of Claims 11-17 and the addition of new Claims 21-32.

Claims 1-10 and 18-32 are under examination. The claims are drawn to more than one invention, a restriction requirement is deemed necessary as set forth below.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 6-10, 21 and 22, drawn to a process for obtaining mature dendritic cells or activated macrophages from monocytes, monocyte precursors or hematopoietic stem cells, comprising contacting monocytes, monocyte precursors or hematopoietic stem cells with R1741470 or an analogue thereof, wherein said R1741470 or analogue thereof when placed in contact with immature dendritic cells induces the functional maturation of the dendritic cells triggering a primary response in vitro against an infectious or tumor antigen placed in contact with the dendritic cells beforehand and/or during their culture with the T lymphocytes; and inducing the proliferation of T lymphocytes in a mixed autologous culture or a mixed allogenic culture, classified in class 435, subclass 372.
- II. Claim 2, drawn to a process for obtaining mature dendritic cells or activated macrophages from monocytes, monocyte precursors or

hematopoietic stem cells, comprising contacting said monocytes, monocyte precursors or hematopoietic stem cells with RU 41470 or an analogue thereof, wherein said RU 41470 or analogue thereof when placed in contact with immature dendritic cells induces a phenotypic maturation of the dendritic cells, by increasing the expression of the molecules CD40, CD83, CD86 and HLA-DR and decreasing the expression of the molecules CD14 and CD 1a, classified in class 435, subclass 372.

- III. Claims 4 and 5, drawn to a process for obtaining mature dendritic cells presenting selected antigens, starting from monocytes, monocyte precursors or hematopoietic stem cells comprising contacting said monocytes, monocyte precursors or hematopoietic stem cells with RU 41470 or an analogue thereof, coupled to molecules comprising the said selected antigens, classified in class 435, subclass 343.
- IV. Claims 18-20, drawn to a composition comprising RU 41470 or an analogue thereof and coupled to antigenic molecules, classified in class 435, subclass 344.1 or class 514, subclass 8, for example.
- V. Claims 23, drawn to a process for producing a composition which modifies an immune response comprising: incubating mature dendritic cells obtained by the process of Claim 1 in the presence of an immunosuppressant to obtain a composition which modifies an immune response, classified in class 514, subclass 885, for example.

- VI. Claims 24 and 25, drawn to a process for producing a composition which modifies an immune response comprising: incubating mature dendritic cells obtained by the process of Claim 2 in the presence of an immunosuppressant a composition which modifies an immune response., classified in class 514, subclass 885, for example.
- VII. Claim 26, drawn to a process for obtaining a composition that can detect and/or characterize histocompatibility antigen comprising: a) obtaining mature dendritic cells using the process of Claim 1; and b) adding the mature dendritic cells to a mixed lymphocyte culture reaction to obtain said composition, classified in class 435, subclass 7.1.
- VIII. Claim 27, drawn to a process for obtaining a composition that can detect and/or characterize histocompatibility antigens comprising: c) obtaining mature dendritic cells using the process of Claim 2; and d) adding said mature dendritic cells to mixed lymphocyte culture reaction to obtain said composition, classified in class 435, subclass 7.1.
- IX. Claim 28, drawn to a process for inducing in vitro the maturation of Langerhans cells comprising topically administering mature dendritic cells obtained by the process of Claim 1, classified in class 424, subclass 556.
- X. Claim 29, drawn to a process for inducing in vitro the maturation of Langerhans cells comprising topically administering mature dendritic cells obtained by the process of Claim 2, classified in class 424, subclass 556.

- XI. Claims 30 and 31, drawn to a process for producing T lymphocytic clones directed against a peptide comprising a) culturing dendritic cells derived from monocytes in the presence of GM-CSF, IL-4 and RU41740 or an analogue of RU41740; b) incubating said culture of a) with a peptide; and c) adding said culture of b) to autologous T lymphocytes to produce lymphocytes specific for said peptide, classified in class 434, subclass 7.24, for example.
- XII. Claim 32, drawn to a process to generate an anatoxin cytotoxic line comprising: a) culturing dendritic cells derived from human monocytes in the presence of GM-CSF, IL-4 and RU41740 or an analogue of RU41740; b) coupling an anatoxin antigen responsible for infection against a microorganism to said dendritic cells obtained in a) to generate an anatoxin cytotoxin line, classified in class 435, subclass 7.24, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III, IV-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different groups are directed to separate and patentably distinct inventions because the methods have been shown to be useful in the making of different end products using different ingredients and different process steps.

The several inventions above are independent and distinct, each from the other. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Inventions III and IV are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product, as evidenced by the claims themselves.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed

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product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele Flood
Primary Examiner
Art Unit 1655

MCF
March 20, 2006


MICHELE FLOOD
PRIMARY EXAMINER